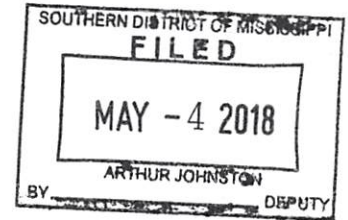


UNITED STATES DISTRICT COURT
for the District of
Southern District of Mississippi



Stephanie S Knoth,

Plaintiff, *pro se*

V.

Jury Trial (Yes)
Case Number 5:18cv49 DCB-MTP

Stephen P Kieth MD;

Gastroenterology Associates;

Southwest Mississippi Regional Medical Center;

Apolla Endoscopy US, Inc.

COMPLAINT
(28 U.S.C. § 1332; Diversity of Citizenship)

I. The Parties to This Complaint

A. The Plaintiff(s)

Name: Stephanie S Knoth
Street Address: 2517 26th Ave
City and County: Forest Grove , Washington County
State and Zip Code: Oregon , 97116
Telephone Number: 971-762-7837
E-mail Address : stephanie.knoth@gmail.com

B. The Defendant(s)

Defendant No. 1:

Name: Dr. Stephen P Kieth
Job or Title: Medical Doctor
Street Address: 300 Rawls DR. Suite 1200
City and County: McComb , Pike County
State and Zip Code: Mississippi 39648
Telephone Number: 601-249-4710
E-mail Address: Unknown

Defendant No. 2:

Name: Southwest Mississippi Regional Medical Center (SWMRMC)
Job or Title: CEO Norman Price
Street Address: 215 Marion Ave.
City and County: McComb, Pike county
State and Zip Code: Mississippi, 39648
Telephone Number: 601-249-5500
E-mail Address: Unknown

Defendant No. 3:

Name: Gastroenterology Associates
Job or Title: Unknown
Street Address: 300 Rawls Dr Suite 1200
City and County: McComb , Pike County
State and Zip Code: Mississippi, 39648
Telephone Number: 601-249-4710
E-mail Address : Unknown

Defendant No. 4:

Name: Apollo Endosurgery US. Inc
Job or Title: CEO
Street Address: 221 W 6th st. STE 700
City and County: Austin, Travis County
State and Zip Code: Texas 78701-3438
Telephone Number: 877-363-6130
E-mail Address apolloendo.com

II. Basis for Jurisdiction

1. Federal courts are courts of limited jurisdiction (limited power). Under 28 U.S.C. § 1332, federal courts may hear cases in which a citizen of one State sues a citizen of another State or nation and the amount at stake is more than \$75,000. In that kind of case, called a diversity of citizenship case, no defendant may be a citizen of the same State as any plaintiff. Explain how these jurisdictional requirements have been met.

A. The Plaintiff(s)

2. If the Plaintiff is an Individual: The plaintiff, Stephanie S. Knoth, is a citizen of the State of Oregon .

B. The Defendant(s)

3. If the Defendant is an individual: The Defendant, Dr. Stephen P Kieth, is a citizen of the State of (Mississippi) .

4. The Defendants, Southwest Mississippi Regional Medical Center, is incorporated under the laws of the State of Mississippi , and has its principal place of business in the State of Mississippi, and has its principal place of business in McComb, Mississippi.

5. The Defendants, Gastroenterology Associates, is incorporated under the laws of the State of Mississippi, and has its principal place of business in the State of Mississippi, and has its principal place of business in McComb, Mississippi.

6. The Defendants, Apollo Endosurgery US. Inc., is incorporated under the laws of the State of Texas, and has its principal place of business in the State of Texas, and has its principal place of business in Texas.

C. The Amount in Controversy

7. The amount in controversy: the amount the plaintiff claims the defendant owes or the amount at stake—is more than \$75,000, not counting interest and costs of court, because Defendant's negligence caused Plaintiff to incur medical bills and damages far in excess of \$75000.00.

III. Statement of Claim

Write a short and plain statement of the claim. Do not make legal arguments. State as briefly as possible the facts showing that each plaintiff is entitled to the damages or other relief sought. State how each defendant was involved and what each defendant did that caused the plaintiff harm or violated the plaintiff's rights, including the dates and places of that involvement or conduct. If more than one claim is asserted, number each claim and write a short and plain statement of each claim in a separate paragraph. Attach additional pages if needed. On (date) , at (place) , the defendant(s): (1) performed acts that a person of ordinary prudence in the same or similar circumstances would not have done; or (2) failed to perform acts that a person of ordinary prudence would have done under the same or similar circumstances because (describe the acts or failures to act and why they were negligent)

8. Plaintiff paid to Southwest Mississippi Regional medical center ("SWMRC" hereinafter), \$8400.00 prepayment for an Obera weight loss 6 month program. Dr Stephen Kieth performed a endoscopy surgery of A Medical device manufactured by Apollo endoscopy " named Obera" balloon # ref# B4800 and serial # 0126127 on 11/29/2016 by endoscopy into Plaintiffs Stomach. Where-in plaintiff became violently ill, Plaintiff requested its removal on 12/01/2016.

9. The doctor did not remove the implanted balloon, but instead removed 4 liters of fluid and repositioned the balloon. this procedure caused aspiration Pneumonia, A ruptured Stomach wall, and Multiple complications from sepsis poisoning.

10. After Multiple surgery's The ruptured stomach remains and is still causing infection into abdomen body cavity. Plaintiff was intubed, became paralyzed, and was induced into a medical coma. Plaintiff has not yet recovered and is in hospital for symptoms caused by rupture of the stomach as of 5/3/2018.

11. The acts or omissions caused or contributed to the cause of the plaintiff's injuries by (explain)

Circumstances Which Brought About the Injury.

12. Appollo endoscopy manufactured a medical device that has caused multiple injuries and death from a weight loss procedure sold as safe and with minimal risk. they failed to disclose the negative results to plaintiff. instad they refer to complications as if they are minimal in risk, such as excessive heartburn and nausea and was administered drugs in advance to treat these conditions.

13. On November 29, 2016, Stephanie Knoth was admitted to Southwest Mississippi Regional Medical Center for an outpatient procedure, the insertion of an Orbera™ intragastric balloon for weight loss. Stephen Keith, M.D., inserted an Orbera™ intragastric balloon as a cosmetic treatment for weight loss. The Directions For Use for Orbera™ includes obtaining a detailed history and physical prior to choosing Orbera™ as a weight loss method.

14. Dr. Keith deviated from the standard of care by not obtaining an adequate History & Physical prior to inserting the Orbera™ intragastric balloon. Dr. Keith failed to obtain informed consent for the Orbera™ balloon. Dr. Keith deviated from the standard of care by failing to disclose the risks listed on the Orbera™ package insert in light of Ms. Knoth's medical history compared to the risks of other surgical treatment options.

15. Dr. Keith performed the procedure beginning at approximately 8:48 a.m. and ended at 9:04 a.m. A 2-centimeter hiatal hernia was noted during balloon insertion. Ms. Knoth was discharged home after the procedure. An EGD was performed on December 1, 2016, at 12:25 p.m. as a planned removal of the Orbera™ balloon per Ms. Knoth's request. However, Dr. Keith noted the balloon was obstructing the pyloric valve with suction removal of 3-4 liters of fluid from the stomach. Dr. Keith chose to leave the balloon intact and only repositioned the balloon.

16. Dr. Keith, failing to exercise reasonable care that another Doctor in the same position would have done, negligently left the Orbera™ balloon in the stomach after discovering the Orbera™ balloon caused a gastric blockage.

17. The "Directions For Use" provides the Orbera Balloon should be removed, if possible, when

gastric outlet obstruction occurs.

18. The negligent retention of the Orbera™ balloon continued to cause damage to the fundus of the stomach and eventually lead to the perforation of the gastric fundus. In addition, Dr. Keith negligently failed to protect Ms. Knoth's airway and prevent aspiration during the "repositioning" balloon procedure. As a result, Ms. Knoth aspirated massive amounts of GI content reading to a life threatening infection and stiffening of lungs known as Acute Respiratory Distress Syndrome (ARDS).

19. Treatment for ARDS, consisted of months of ventilator dependence, a tracheostomy tube and chest tubes to clear the infection caused by the aspiration. An abdominal assessment by Dany Haddad, M.D., included a finding that Ms. Knoth's abdomen was distended and firm, with guarding.

20. Dr. Haddad also noted Ms. Knoth continued to complain of nausea and vomiting, dyspnea, cough and noted she appeared ill and weak.

21. Dr. Haddad advised Dr. Keith that Ms. Knoth wanted the gastric balloon removed. Post-procedure diagnosis included a Mallory Weiss tear and 3 centimeter fundal ulcer. There are two dates, December 8, 2016 and December 9, 2016, at 9:30 p.m., both documented by Dr. Keith, as the possible dates an EGD was done for a diagnosis of Acute Abdomen, acute onset abdominal pain.

22. The Orbera™ balloon was removed and a perforation of the fundus was noted. Dr. Keith documented a "perforation and septic on CT". Ms. Knoth was intubated on December 9, 2016, and remained on a ventilator until her transfer to Ochsner Medical Center in New Orleans on December 17, 2016. Sputum cultures were not collected until December 13, 2016.

23. On December 15, 2016, sputum Gram Stain and cultures revealed positive for Moderate amount *Stenotrophomonas maltophilia*. When Stephanie Knoth began to have nausea and vomiting with the presence of an ulcer, Dr. Keith should have removed the Orbera™ balloon pursuant to manufacturer guidelines and as instructed by plaintiff.

24. Instead, Dr. Keith deviated from the standard of care by leaving the intragastric balloon in place. The improperly retained Orbera™ balloon ruptured, leaking 1 liter of contaminated saline into

the peritoneal space by way of the gastric perforation.

25. The particulate matter and contaminated saline caused a serious life-threatening peritonitis. It is also factually significant, that the dates Dr Kieths record of events reflect a December 2nd date, 2016 as the date of the endoscopy to remove the balloon. (However it was not removed) The actual dates are December 1, 2016. As is evidenced by the medical records of plaintiff. Our belief is that the doctor intended to hide the actual date to prevent plaintiffs access to multiple witnesses present in the operating room during the procedure.

II. Extent of Injury

26. Pursuant to the hospital records, Ms. Knoth sustained a gastric perforation from the insertion and negligent retention of the Orbera™ balloon leading to respiratory failure that required long-term ventilator support and a tracheostomy. In addition, the gastric leak of contaminated fluids lead to septic shock, pneumonia and peritonitis.

27. Due to the repeated surgeries required to treat the abdominal infection, Ms. Knoth has extensive scarring and disfigurement. As a result of the acts and omissions of Southwest Mississippi Regional Medical Center, Gastroenterology Associates, and Stephen Keith, M.D., Ms. Knoth suffered irreparable and extensive injuries both physically and emotionally.

III. Time and Place the Injury Occurred

28. Ms. Knoth suffered injuries on November 29, 2016, beginning at approximately 09 AM at Southwest Mississippi Regional Medical Center, 215 Marion Avenue, McComb, Mississippi 39648 and ending at approximately 10 AM p.m. on December 17, 2016 at Southwest Mississippi Regional Medical Center, 215 Marion Avenue, McComb, Mississippi 39648.

IV. Name of all Persons Known to be Involved

29. All persons identified in this notice are known to be involved to the extent stated therein including Stephanie Knoth, Stephen Keith, M.D., Dany Haddad, M.D., and others that discovery may reveal. All persons identified in the medical records, including all nurses or other medical personnel of

Southwest Mississippi Regional Medical Center and/or Gastroenterology Associates, as well as medical personnel of other medical facilities, are known to be involved to the extent stated therein.

IV. Relief

30. Plaintiff is still fighting infection and still has a hole in stomach. resulting in multiple emergency room visits and repeated hospital procedures, major Surgery's, and admissions to resolve the perforation. As to date of 5/3/2018, the perforation has not been repaired. plaintiff still suffers from Pertinacious infection, Lung Damage, Ill Health, Shortness of breath, Low energy and is disfigured. Plaintiff has always enjoyed exceptional health before this procedure.

31. Plaintiff asks for Apollo Endoscopy Inc., to cease marketing Obara as it is a defective product, heavily marketed as a safe weight loss system. this is fraudulent and misrepresented in the marketing by Apollo endoscopy SW MRMC and Dr. Keith.

32. Plaintiff asks Apollo Endoscopy Inc. to train doctors in removing existing implanted Obara (tm) Balloons to prevent poisoning of patients. The Balloon has a history of becoming infected with Bacteria that when introduced into the human body, produces serious and fatal infections. The Obara (tm) Balloon also has significant history of expanding above the original placement. This has not been explained to date. However several Stomachs have been damaged resulting in death, disfigurement, removal of stomach and other unacceptable complications

33. Plaintiff asks for return of All money paid to SWMRMC for prepayment of procedure on 1/28/2016 Apx \$8400.00.

34. Plaintiff asks for Damages 5,000,00. 00 Or an Amount court finds equitable and fair.

35. Plaintiff Asks for Damages of all Medical expenses already incurred and future medical expenses in the amount of 3,000,000.00 . or the amount the court finds equitable and fair.

36. Plaintiff asks for punitive damages of 3 times the Amount of equitable damages to act as a

determent to defendants ignoring plaintiffs request. or the amount the court finds equitable and fair.

37. Plaintiff Asks for Damages of \$5,000,000. 00 for pain and suffering. or the amount the court finds equitable and fair.

V. Certification and Closing

Under Federal Rule of Civil Procedure 11, by signing below, I certify to the best of my knowledge, information, and belief that this complaint: (1) is not being presented for an improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation; (2) is supported by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law; (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery; and (4) the complaint otherwise complies with the requirements of Rule 11.

A. For Parties Without an Attorney

I agree to provide the Clerk's Office with any changes to my address where case-related papers may be served. I understand that my failure to keep a current address on file with the Clerk's Office may result in the dismissal of my case.

Date of signing:05/03/2018



Signature of Plaintiff

Printed Name of Plaintiff: Stephanie S. Knoth